ENDOSCOPIC DEVICE FOR SPILL-PROOF LAPAROSCOPIC OVARIAN CYSTECTOMY

Cross-Reference to Related Application

[0001] This application is a continuation-in-part of U.S. Application Serial No. 10/147,261, filed May 15, 2002, the entirety of which is hereby incorporated by reference.

Background of the Invention

Field of the Invention

[0002] The invention relates in one embodiment to a method of performing an ovarian cystectomy by laparoscopy using a spill-proof endoscopic device. A spill-proof endoscopic device is also disclosed.

Description of the Related Art

[0003] Within the context of one embodiment of the present invention, ovarian cystectomy refers to the removal of a cyst from an ovary. Laparotomy refers to the traditional method of opening up the abdomen by making a large incision, typically about 12-14 cm in length. Oophorectomy is defined as the removal of the entire ovary. Laparoscopy is a method of performing intra-abdominal surgery via very small incisions, often 1 cm or less in length. Laparoscopic ovarian cystectomy is the removal of a cyst from the ovary using the technique of laparoscopy.

[0004] Ovarian cystectomy is a commonly performed procedure in gynecology. An attendant risk to this procedure, especially if done via laparoscopy, is the accidental leakage of the cyst content into the peritoneal cavity, which occurs most often during the separation of the cyst from the ovary. This can worsen the prognosis if the cyst turns out to be malignant or can lead to peritonitis if the cyst is a dermoid or mucinous cyst. Because of this hazard, ovarian cystectomy by laparoscopy requires more skill, time, and effort than that done via laparotomy if the cyst is to be removed without spillage. Consequently, many surgeons will opt to go directly to a laparotomy or perform a laparoscopic oophorectomy (which has a much lower risk of cyst leakage because the cyst is not separated from the ovary) instead of a laparoscopic cystectomy if he or she is uncertain about the nature of the cyst.

[0005] In addition, there is often no way to know in advance if the cyst is malignant, dermoid, mucinous, or otherwise. The physician must rely upon a combination of imprecise diagnostic indicators and guess work to determine whether or not a laparoscopic cystectomy can be safely attempted. This uncertainty and the fear of spillage cause many physicians not to attempt laparoscopic ovarian cystectomy or to feel very uncomfortable doing it.

[0006] Thus, a need exists for methods and apparatuses for performing a laparoscopic ovarian cystectomy safely and easily, without spilling the contents of the cyst into the peritoneal cavity. This will reduce the number of patients who suffer the harmful consequences of cyst spillage. This will also allow more laparoscopic ovarian cystectomies, instead of laparotomies or oophorectomies, to be performed.

[0007] The prior art discloses several types of endo-bags for use during a laparoscopic procedure. U.S. Patent No. 5,215,521 to Cochran et al. discloses an entrapment envelope which is inserted through a laparoscopic port for removal of a surgically severed organ.

[0008] U.S. Patent No. 6,059,793 to Pagedas discloses a reusable bag for retrieval of a mass, such as an excised organ, through a laparoscopic sleeve and also allows for morsellizing the severed organ.

[0009] U.S. Patent No. 6,270,505 to Yoshida et al. discloses an inflatable endo-bag for organ removal, ports for surgical instruments and a closing string.

[0010] All of the prior art references discussed above are drawn to encapsulation of an organ after it has been surgically severed from its attachments to the body. In particular, all of these prior art references address the problem of transport of an organ outside the abdominal cavity after it has been laparoscopically excised inside the abdominal cavity. Accordingly, these prior art references do not address the special problem of separating a mass, such as a cyst, from a live, intact organ such as an ovary without rupture of the cyst and spillage of its contents.

[0011] U.S. Patent No. 5,279,539 to Bohan et al. discloses a bioabsorbable surgical pouch which can be placed over an ovary after a surgical procedure to prevent

surgical adhesions. However, Bohan et al. do not disclose the use of the pouch during a surgical procedure such as performing an ovarian cystectomy.

[0012] There are typically two steps involved in the removal of an ovarian cyst by laparoscopy. The first step is the separation of the cyst from the ovary. The second step is the transport of the cyst outside of the abdominal cavity once it has been separated from the ovary. There are problems associated with each step. The problem in the first step is how to separate the cyst from the ovary without rupturing the cyst and spilling its contents. The problem with the second step is how to transport a large cyst outside the abdominal cavity through a small opening in the abdomen. All of the prior art discussed above are involved only with the problem associated with the second step, that is, transport of a mass or organ outside the abdomen after it has been excised.

Summary of the Invention

[0013] Preferred embodiments of the present invention address the first problem, specifically, separation of a mass such as a cyst from an ovary without spilling its contents into the abdominal cavity. It will be appreciated, however, that the methods and apparatuses discussed herein are not limited to ovarian cystectomies, and therefore, may have applicability to any procedure wherein it is desired to remove biological or other material from an organ, or to remove an organ itself, in a contained environment.

[0014] Several unique features are disclosed by the preferred embodiments discussed below. First, in one embodiment, an intact organ is encapsulated, preferably with a non-permeable bag-type or other expandable structure, while it is still attached to the body. As used herein, an intact organ is defined as an organ that is still attached to the body as found in its natural state. The intact organ is preferably a live intact organ. However, intact organs which contain dead tissue are also encompassed within the present invention. The encapsulation of an intact organ is in contrast to the prior art references discussed above, wherein encapsulation can only occur after the organ or mass has been completely separated from its attachment to the body. Thus, in the prior art discussed above, the organ or mass is first completely excised and then encapsulated. In preferred embodiments of the present invention, the organ or mass is first encapsulated and then the process of excision is performed. These embodiments advantageously allow a mass, such as an ovarian cyst, for

example, to be separated from the ovary without spilling its contents into the abdominal cavity.

[0015] In one embodiment, the disclosed bag or other expandable structure surrounding the intact organ is provided with multiple openings for insertion of one or more instruments. These instruments may be inserted simultaneously to perform operations on an intact organ such as removal of a cyst from an ovary, or other desired procedures. In one embodiment, openings are provided with a one-way valve. In other embodiments, the expandable structure expands to form a bowl or cup and is placed underneath the intact organ. In these alternative embodiments, the expandable structure does not completely enclose the intact organ.

[0016] In one embodiment, the bag is a balloon-like structure designed to prevent spillage of the cyst content into the peritoneal cavity and thus make laparoscopic ovarian cystectomy safe and easy. The balloon-like structure preferably comprises an inflatable, water-tight, fire-retardant bag with an opening on a distal side thereof and a gas nozzle on a proximal side thereof. In a preferred embodiment, the bag is funnel-shaped and has a large noose-like opening at the distal end. In one embodiment, the proximal end is long and tapered. In a preferred embodiment, the distal end has a relatively large opening, at least large enough to encapsulate an ovary or other organ.

[0017] The bag in one embodiment used for laparoscopic ovarian cystectomy is introduced into the peritoneal cavity through a laparoscopic port, the proximal end with the gas nozzle being retained on the outside of the body for gas infusion. Once inside the peritoneal cavity, the large distal opening of the bag is then placed over the ovary and fastened. In a preferred embodiment, a noose is tightened down over the ovarian pedicle and locked in using a fastening device such as a trumpet valve. As used herein, the term "pedicle" is used in its ordinary sense and refers to any stem-like structure that extends from an organ. The term "ovarian pedicle" is used in its ordinary sense and should be interpreted to include a combination of the infundibulo-pelvic ligament, the utero-ovarian ligament and/or the meso-ovarian ligament. In the presence of an ovarian cyst, these tissues can become elongated to form a slender stem-like structure that is herein referred to as the ovarian pedicle. Tightening the noose around this ovarian pedicle allows the bag to

completely envelop the ovary and its cyst and form an air-tight seal. In a preferred embodiment, gas is then infused through the gas nozzle to inflate the bag.

[0018] In a preferred embodiment, a laparoscopic camera and other instruments can now be passed into the inflated bag through one-way valves to operate on the cyst. Any leakage of cyst content during the surgery is now contained within the bag and therefore does not come into contact with the peritoneal cavity and its organs. In a preferred embodiment, the cyst can be deflated without any concern for contamination and the cystectomy performed much easier and faster on a collapsed cyst. An additional advantage of the bag is that it also prevents accidental and harmful contact between the laparoscopic instruments and other organs such as the bowel or bladder.

[0019] After the cystectomy is completed, any fluid leakage into the bag is removed by laparoscopic suction and the bag thoroughly irrigated. The noose is then loosened and the ovary removed from the bag. The noose is closed again and the bag, containing the specimen, is removed from the peritoneal cavity through a laparoscopic port.

[0020] The preferred methods and apparatuses described above and in further detail below allow for a safe, rapid and easy laparoscopic ovarian cystectomy because it circumvents the most difficult and time-consuming aspect of the surgery, i.e., the prevention of cyst spillage into the peritoneal cavity.

[0021] For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention have been described above. Of course, it is to be understood that not necessarily all such objects or advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art may recognize that the invention may be embodied or carried out in a different manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

[0022] Accordingly, in one embodiment, a surgical device is disclosed for enclosing an intact organ to perform a surgical procedure thereon. The device includes a non-permeable material adapted to be closed over an intact organ while substantially enclosing the intact organ and at least one port in the non-permeable material adapted to

allow a surgical instrument to pass therethrough to operate on the intact organ. In a preferred embodiment, the non-permeable material is an inflatable bag and preferably includes a nozzle at one end for inflating the bag while the material is closed over the intact organ.

[0023] In a preferred embodiment, the intact organ is an ovary.

[0024] In one embodiment, a surgical device for enclosing an intact organ to perform a surgical procedure thereon is disclosed which includes an inflatable bag comprising flexible material and having an opening at a distal end thereof sufficiently large to receive the intact organ and a nozzle at a proximal end thereof adapted to inflate the bag and at least one port which includes a one-way valve to allow a surgical instrument to be introduced into the bag to perform a surgical operation on the intact organ contained within the bag without leakage of gas. In a preferred embodiment, the intact organ is an ovary.

[0025] In a preferred embodiment the surgical device includes an insertion housing for enclosing the bag. In a preferred embodiment, the surgical device also includes a plurality of ports to allow surgical instruments to be introduced into the bag.

[0026] In another preferred embodiment, the invention includes a surgical device for enclosing an intact organ to perform a surgical procedure thereon, the device including:

an expandable structure having a collapsed configuration and an expanded configuration;

a membrane attached to the expandable structure; and

at least one port in the membrane adapted to allow a surgical instrument to pass therethrough to operate on the intact organ.

[0027] In a preferred embodiment, the membrane of the surgical device which is attached to the expandable structure is substantially funnel-shaped when the expandable structure is in its expanded configuration.

[0028] Preferably, the intact organ is a live intact organ. More preferably, the intact organ is an ovary. In a preferred embodiment, the membrane is adapted to be closed over a pedicle of the intact organ.

[0029] In a preferred embodiment, the expandable structure is self-expanding. Preferably, the expandable structure includes a plurality of self-expanding struts.

[0030] Preferred embodiments of the invention include a surgical device for enclosing an intact organ to perform a surgical procedure thereon, which includes:

an expandable structure including a plurality of struts;

a membrane attached to the struts, having an opening at a distal end thereof sufficiently large to receive the intact organ and an attachment point at a proximal end thereof adapted to manipulate and retrieve the expandable structure; and

at least one port to allow a surgical instrument to be introduced into the expandable structure to perform a surgical operation on the intact organ contained within the expandable structure.

[0031] In a preferred embodiment, the struts are self-expanding. In some preferred embodiments, the struts include spring-loaded metal prongs. In a preferred embodiment, the attachment point is a flexible loop.

[0032] Preferably, the intact organ is a live intact organ. More preferably, the intact organ is an ovary.

[0033] In a preferred embodiment, the surgical device includes a drawstring near the opening to close the opening. In a preferred embodiment, the opening at the distal end is a noose-like opening. Preferably, the surgical device includes an insertion housing for enclosing the expandable structure. Preferably, the surgical device includes a plurality of ports to allow surgical instruments to be introduced into the expandable structure.

[0034] In another embodiment a method of performing a cystectomy is disclosed which includes the steps of: (1) introducing an inflatable bag into an abdominal cavity of a patient, wherein a distal end of the inflatable bag has an opening sufficiently large to encapsulate an ovary which is attached to the body; (2) positioning the inflatable bag over the ovary to encapsulate the ovary; (3) closing the opening of the inflatable bag over an ovarian pedicle; (4) inflating the bag; and (5) introducing one or more instruments into the bag to separate a cyst from the encapsulated ovary.

[0035] In a preferred embodiment, the method includes inserting the bag into the abdominal cavity within an insertion housing.

[0036] In another embodiment, a method of performing an operation on an intact organ, is disclosed which includes the steps of: (1) introducing a non-permeable structure into

a body space near to the intact organ; (2) enclosing at least a portion of the intact organ with the non-permeable structure, the non-permeable structure defining a working space between the intact organ and the non-permeable structure; and (3) introducing one or more instruments through the non-permeable structure to perform the operation on the intact organ within the working space. In some embodiments where the intact organ is only partially enveloped, the instruments do not have to pass through the non-permeable structure in order to access the intact organ.

[0037] Other preferred embodiments of the invention include a method of performing a cystectomy, which includes the steps of:

introducing an expandable structure having a frame attached to a membrane capable of having a collapsed configuration and an expanded configuration into an abdominal cavity of a patient;

expanding the frame attached to the membrane to the expanded configuration to provide an opening at the distal end of the frame sufficiently large to encapsulate an ovary which is attached to the body;

positioning the frame over the ovary to encapsulate the ovary;

closing the opening of the expandable structure over an ovarian pedicle; and

introducing one or more instruments into the expandable structure to separate a cyst from the encapsulated ovary.

[0038] In a preferred embodiment, the method includes removing the expandable structure from the ovarian pedicle and releasing the ovary from the expandable structure. More preferably, the method includes re-closing the opening of the expandable structure with the ovary outside the expandable structure and with the removed cyst inside the expandable structure. More preferably, the method includes transporting the separated cyst outside of the abdominal cavity within the expandable structure.

[0039] In a preferred embodiment, the method includes introducing the expandable structure into the abdominal cavity comprises inserting the expandable structure into the abdominal cavity within an insertion housing.

[0040] In a preferred embodiment, the expandable structure is opened sufficiently to allow for the performance of the cystectomy inside the expandable structure.

[0041] In a preferred embodiment, closing the opening of the expandable structure over the pedicle is performed by pulling a drawstring closed over the ovarian pedicle.

[0042] In a preferred embodiment, introducing one or more instruments into the expandable structure is performed by inserting said instruments through ports in a surface of the membrane.

[0043] In other embodiments, the surgical device for performing a surgical procedure, includes an expandable structure including a plurality of struts, and a membrane attached to the struts, having an opening at a distal end thereof and an attachment point at a proximal end thereof adapted to manipulate and retrieve the expandable structure, wherein the expandable structure in an expanded configuration forms a bowl to collect leakage from the surgical procedure.

[0044] In some embodiments, the struts include spring-loaded metal prongs. In preferred embodiments, the struts are self-expanding. Preferably, the attachment point includes a flexible loop. Preferably, the surgical device also includes an insertion housing for enclosing the expandable structure.

[0045] In some embodiments, a method of performing a cystectomy is disclosed which includes the steps of:

introducing an expandable structure capable of having a collapsed configuration and an expanded configuration into an abdominal cavity of a patient;

expanding the frame attached to the membrane to the expanded configuration to provide a bowl;

positioning the bowl underneath an ovary to collect leakage from the cystectomy;

separating a cyst from the ovary; and

suctioning the leakage from the bowl.

[0046] Preferably, the step of introducing the expandable structure into the abdominal cavity includes inserting the expandable structure into the abdominal cavity within an insertion housing. Preferably, the expandable structure includes a frame attached to a membrane.

[0047] Further aspects, features and advantages of this invention will become apparent from the detailed description of the preferred embodiments which follow.

Brief Description of the Drawings

[0048] These and other feature of this invention will now be described with reference to the drawings of preferred embodiments which are intended to illustrate and not to limit the invention.

[0049] FIGURE 1A is a perspective view of a bag according to one embodiment of the present invention.

[0050] FIGURE 1B is a perspective view of a bag having a trumpet valve according to another embodiment of the present invention.

[0051] FIGURE 2 is a side view of an insertion housing for inserting the bag of Figure 1A or 1B, with the bag shown inside the insertion housing in phantom.

[0052] FIGURE 3 is a schematic view of the bag of Figure 1A after insertion into the abdomen via the suprapubic port under visualization by a laparoscopic camera.

[0053] FIGURE 4 is a schematic view of the bag of Figure 3 after placement around an ovary and cyst and after a noose on the bag has been tightened down.

[0054] FIGURE 5 is a schematic view of instruments inserted into the inflated bag through one-way valves under guidance by the laparoscopic camera.

[0055] FIGURE 6A is a schematic view of the inflated bag within the abdominal cavity, showing the laparoscopic instruments and camera inside the bag, ready to operate on the cyst.

[0056] FIGURE 6B is a schematic view showing surgery inside the bag, in this case, puncturing and decompressing the cyst.

[0057] FIGURE 7 is a schematic view of the interior of the bag after the cyst has been separated from the ovary and the spilled cyst content is being removed from the bag via laparoscopic suction.

[0058] FIGURE 8 is a schematic view of the bag after deflation, wherein the instruments and the ovary are removed from the bag, the noose is tightened down to close the bag and the gas nozzle is inserted into the abdomen.

[0059] FIGURE 9 is a schematic view of the deflated bag containing the cyst as it is removed from the abdomen through a laparoscopic port.

[0060] FIGURE 10 is a schematic view of a self-expanding endoscopic bag for spill-proof laparoscopic ovarian cystectomy.

[0061] FIGURE 11 is a schematic view of the self-expanding endoscopic bag for spill-proof laparoscopic ovarian cystectomy of Figure 10 within an insertion housing.

[0062] FIGURE 12 is a schematic view of the self-expanding endoscopic bag for spill-proof laparoscopic ovarian cystectomy of Figure 10 placed around an ovary with the noose tightened around the ovarian pedicle.

[0063] FIGURE 13 is a schematic view of the self-expanding endoscopic bag for spill-proof laparoscopic ovarian cystectomy of Figure 10 after the cyst is removed and fluid has been suctioned out.

[0064] FIGURE 14 is a schematic view of the self-expanding endoscopic bag for spill-proof laparoscopic ovarian cystectomy of Figure 10 as it is pulled into the trochar sleeve.

[0065] FIGURE 15 is a schematic view of an expandable endoscopic bag for spill-proof laparoscopic ovarian cystectomy.

[0066] FIGURE 16 is a schematic view of the expandable endoscopic bag of Figure 15 during an ovarian cystectomy.

Detailed Description of the Preferred Embodiments

[0067] While the described embodiments represent preferred embodiments of the present invention, it is to be understood that modifications will occur to those skilled in the art without departing from the spirit of the invention. The scope of the invention is therefore to be determined solely by the appended claims.

[0068] Briefly stated, preferred embodiments relate to a bag or expandable structure used to at least partially encapsulate an ovary for performing a cystectomy, and methods for delivering the bag or expandable structure and for performing the cystectomy. The bag or expandable structure may encapsulate the ovary or may provide a bowl-like structure underneath the ovary to collect leakage and other materials that result from the operation. It will be appreciated, however, that the methods and apparatuses taught herein

are not limited to ovarian cystectomies, and thus, other procedures may benefit from the embodiments described herein.

[0069] Figure 1A shows one embodiment of a bag **10** to be used to perform the cystectomy. The bag as illustrated is generally funnel-shaped and has a proximal end **12** and a distal end **14**. At the distal end **14**, an opening **16** is provided which is sized and configured to fit over an organ such as an ovary. As illustrated, the opening **16** can be circular, or may have any other shape as desired that is adapted to form a substantially air tight seal with a portion of an organ such as an ovarian pedicle. In one embodiment, a drawstring **18** is provided near the edge of the opening **16**, and is adapted to be pulled taut over a tissue pedicle to seal and lock the bag. The drawstring **18** may be made of any stretchable, rubber-band-like material or non-stretchable material including but not limited to an elastic band, rubber band, suture material, etc., or any other desired material.

[0070] In the embodiment illustrated in Figure 1A, to close the bag over a pedicle, the drawstring **18** is pulled through a noose **20** to seal and lock the bag. Other embodiments may also be used to seal and lock the bag, such as a noose over a button, a velcro fastening or a pre-tied suture. Figure 1B illustrates one embodiment wherein the drawstring **18** can be closed using a trumpet valve **22**. It will be appreciated that other means may be used to seal the bag **10**. In one embodiment, closure of the opening **16** of the bag **10** over a tissue pedicle may be further reinforced with a separate rubber band placed around the outside of the bag near the opening **16**.

[0071] The bag itself may be made of any flexible material that is capable of being blown up like a balloon including, but not limited to, plastic material, latex, or rubber. The balloon material may be compliant in order to fill the desired space within the patient, or may be non-compliant to inflate to a predetermined size. It will be appreciated, however, that the invention is not to be limited to inflatable structures. Any non-permeable structure capable of isolating an organ to be treated from surrounding organs or bodily space will be suitable in performing the cystectomy or other procedure. For example, expandable structures (both self-expanding and non-self-expanding) may be used.

[0072] At the proximal end **12** of the bag **10**, away from the opening **16**, the bag preferably tapers into a long tube **24**. At or near the very proximal end of the tube **24**, a gas

nozzle **26** may be provided to allow for inflation of the bag. The tube **24** and the gas nozzle **26** are preferably adapted to extend outside of the body and allows for infusion of gas to blow up the bag **10** when the opening is sealed over a tissue pedicle. The gas nozzle **26** preferably includes a one-way valve to allow gas or other fluid to be delivered into the bag and maintain inflation of the bag.

[0073] As illustrated in Figure 1A, the bag may also have additional openings or ports **28, 30,** and **32** (see also Figures 3-9) to allow for insertion of surgical instruments, as described below. These ports **28, 30,** and **32** may be placed at desired locations on the outside of the bag to allow for the insertion of appropriate surgical instruments at desired locations. Preferably, each of these ports includes a one-way valve, as described below, to prevent gas inside the bag from escaping when an instrument is inserted therethrough.

[0074] Figure 2 illustrates an insertion housing **34** used in one embodiment to insert the bag **10** into a patient. The insertion housing preferably includes a tubular body **36** having a proximal end **38** corresponding to the proximal end **12** of the bag **10**, and a distal end **40** corresponding to the distal end **14** of the bag **10**. The insertion housing may be made of any relatively hard, biologically non-reactive material including but not limited to plastic materials. Figure 2 illustrates the bag **10** inside the insertion housing **34** before insertion into the body in a compressed configuration. The distal end **40** of the housing is preferably open and the proximal end **38** of the housing is preferably closed prior to delivery of the bag **10**. Further details regarding delivery of the bag into a patient using the insertion housing **34** are described below.

[0075] Figure 3 illustrates one embodiment for inserting the bag **10** into the peritoneal or abdominal cavity **48** of a patient **50**. As illustrated, a plurality of incisions ranging from 5-10 mm **52, 54, 56, 58** are made in the patient **50**. Then, using standard laparoscopic techniques, trocars and trocar sleeves are inserted into the abdomen. After the trocars are removed, the trocar sleeves **60, 62, 64** and **66**, as described further below, remain extending from the outside of the patient. The trocar sleeves **60, 62, 64** and **66** each preferably includes a one-way valve such that when instruments are passed through the trocar sleeves into the abdomen of the patient, gas from inside the abdomen, as described below, does not escape. The trocar sleeves described in the embodiments herein preferably have a

size of 5 mm or 10 mm. However, it will be appreciated that any size trocar sleeve may be used that is appropriate to carry out the surgical procedure. Different ports and adapters may also be used as needed.

[0076] In the embodiment illustrated in Figure 3, the laparoscope **68** is preferably inserted into the abdomen through a trocar sleeve **60** near the navel. Gas, preferably carbon dioxide, is introduced into the abdominal cavity via one of the trocar sleeves, such as sleeve **60**. The intra-abdominal pressure is preferably maintained at a constant level using well-known methods and apparatus.

[0077] The bag **10** is preferably introduced into the abdominal cavity **48** through a second 5 or 10 mm trocar sleeve **62** via a suprapubic incision **54** or any other location as desired by the surgeon. In one embodiment, the insertion housing holding the bag, described above, is inserted through the trocar sleeve **62** until its distal end **14** (corresponding to the opening of the bag **16**) enters the abdominal cavity as shown in Figure 3. In a preferred embodiment, the outer diameter of the housing is a perfect fit with the inner diameter of the trocar sleeve **62** such that when the housing is passed through the trocar sleeve, CO_2 gas from within the abdomen is prevented from escaping due to the housing **34** being sealed at its proximal end **38**.

[0078] After the housing is delivered through the trocar sleeve **62** into the abdomen, the bag is then grasped from the distal end of the insertion housing with a laparoscopic grasper **78** while the insertion housing **34** is pulled out, leaving the gas nozzle **26** on the outside of the body. Preferably, the gas nozzle **26** will be of such size and material such that it will form a tight seal with the one-way valve of the trocar sleeve **62**. A 10-5 mm seal reducer may be used if necessary to achieve a tight seal. It will be appreciated that other methods and apparatuses may be used to insert the bag **10** into the abdomen **48** of a patient **50**.

[0079] As shown in Figure 4, in performing an ovarian cystectomy, once inside the abdominal cavity the bag **10** is preferably maneuvered such that the opening **16** of the bag **10** is placed over the ovary **72** having a cyst **74** and the ovarian pedicle **82**. Positioning of the bag is facilitated by the use of laparoscopic instruments **76** and **78** that can be inserted into the abdomen. In one embodiment, ports **28, 30,** and **32** containing one-way valves on the bag

10 are generally lined up, respectively, with the trocar sleeves **66**, **64**, and **60**, extending into the patient's abdomen, so that the laparoscope **68** and other laparoscopic instruments **76**, **78** passing through these sleeves can be directly inserted into these ports **28**, **30**, and **32**. The bag **10** may also have one or more external markings **80** to help guide the alignment of the ports on the bag **28**, **30**, **32** with the trocar sleeves **66**, **64**, and **60**. As shown in Figure 4, a mark **80** on the bag **10** may be used to align the port **32** with the trocar sleeve **60** and the laparoscope **68**.

[0080] Once the opening **16** is positioned over the ovary **72** and the ovarian pedicle **82** and the bag is properly aligned, the opening is closed over the ovarian pedicle as shown in Figure 4. Closure can occur using a noose **20** or other methods as described with respect to Figures 1A and 1B above. Laparoscopic instruments such as grasping forceps **76**, **78** may be used to assist in closing the bag **10**.

[0081] Gas, preferably carbon dioxide, is then infused into the bag **10** via the gas nozzle **26** to inflate the bag. The bag **10** may be inflated as required to provide a space to perform the surgery and in one embodiment, may be inflated up against the abdominal wall **48**.

[0082] With the bag inflated, the ports **28**, **30** and **32** on the bag are preferably aligned with the incisions **58**, **56** and **52** and the trocar sleeves **66**, **64** and **60**, respectively. If the bag is not properly aligned upon initial inflation, the physician can use grasping instruments such as grasping forceps **76**, **78** which are inserted into the abdominal cavity **48** but have not yet been inserted into the bag to finalize the alignment of the bag.

[0083] Figure 5 illustrates the bag after it has been inflated in the abdominal cavity **48** with instruments inserted into the bag **10**. The laparoscope remains outside of the bag **10**, but inside the abdominal space to allow the operator to visualize where the instruments will be inserted through the bag. Instruments, including but not limited to grasping forceps, blunt probes, needle electrodes or laparoscopic scissors, etc. may be inserted into the ports **28** and **30** on the bag **10**. Each of these ports **28** and **30** preferably includes a one-way valve to allow for insertions of the instruments without leakage of gas.

[0084] As shown in Figures 6A and 6B, after the instruments **76** and **78** are inserted into the bag **10**, the laparoscope **68** is then inserted through a port **32** in the bag **10** to

provide visualization for the procedure inside the bag **10**. The cystectomy or other procedure is then performed under direct visualization by methods well known to those skilled in the art. More instruments may be inserted into the bag to help facilitate the procedure if so desired by the surgeon.

[0085] In one preferred embodiment, after the laparoscope **68** and instruments **76** and **78** are inserted into the bag **10**, the cyst **74** can safely be punctured and deflated before excision using one of the instruments (Figure 6B). This is in contrast to procedures performed in the past, where physicians would use great care not to puncture the cyst to avoid leakage into the peritoneal cavity. In this embodiment of the invention, any leakage of fluid is advantageously contained within the bag. This allows the cystectomy to be safely and easily performed by the laparoscopic method, regardless of the nature of the cyst. In fact, no matter what type of cyst is present, with the preferred embodiments of the invention described above, there is no leakage of fluid into the peritoneal cavity. Consequently, even an inexperienced surgeon can perform a laparoscopic ovarian cystectomy using the bag described above because any fluid leakage from a malignant, dermoid or mucinous cyst is retained safely within the bag. Another advantage with a preferred embodiment of the invention is that because of the ability to deflate the cyst safely, even a very large cyst which formerly would have required a laparotomy even by an experienced surgeon, can now be easily removed by laparoscopy.

[0086] Once the cyst is punctured and the fluid has leaked out, the cyst **74** often becomes easier to remove from the ovary **72**. As shown in Figure 7, the punctured cyst **74** can be removed and separated from the ovary using known techniques. Alternatively, should the surgeon prefer, the cystectomy can proceed without first deflating the cyst. However any accidental cyst leakage during the procedure would still be contained within the bag **10**. In a preferred embodiment, any spillage **84** caused by the procedure is removed with a laparoscopic suction-irrigator **86** and the bag is thoroughly cleansed with irrigation. In one embodiment, a suction-irrigator **86** is inserted through one of the ports **30** in the bag **10** to irrigate and remove any loose substances or fluid. After irrigation and suction of the fluid in the bag, the instruments **76**, **86** and laparoscope **68** may be removed through the ports **28, 30,** and **32**.

[0087] As shown in Figure 8, after irrigation, suction, and instrument removal, the bag is deflated while the noose over the ovarian pedicle **82** is loosened to allow removal of the ovary **72** from the bag **10**. The noose **20** can then be tightened again using the surgical instruments **76, 78** which are now outside the bag but still within the abdominal space to seal off the bag **10** with the excised cyst **74** inside as shown in Figure 8. In a preferred embodiment, as described above, the cyst **74** has been punctured and deflated. Consequently, it is now much smaller and the bag **10** containing it may be easily removed through one of the trocar sleeves. However, in some embodiments where the tissue mass is still large, it may be desirable to reduce the size of the tissue prior to deflating the bag by grinding the tissue with an instrument designed for that purpose such as a morsellizer (see U.S. Patent No. 6,059,793 to Pagedas which is incorporated herein by reference).

[0088] The bag is desirably removed through one of the trocar sleeves inserted through one of the laparoscopic incisions. In one embodiment, the tube **24** and the gas nozzle **26** of the bag **10** are pushed into the abdomen as shown in Figure 8. Figure 9 shows removal of the deflated bag **10** containing the cyst **74** through the trocar sleeve **66**. It will be appreciated that the bag can be removed through any of the trocar sleeves. In a preferred embodiment, the bag is grabbed by the tightened noose **20** and the bag **10** with cyst **74** can be easily removed without contamination of the peritoneal cavity.

[0089] Figure 10 shows an alternate embodiment of an expandable structure used for spill-proof laparoscopic ovarian cystectomy. The expandable structure **110** includes a plurality of struts **88** defining a frame with a membrane **90**, more preferably made of a non-permeable material, attached to the struts **88**. The plurality of struts **88** have a common proximal point **92** and extend towards the distal end **94** of the structure but are not attached at the distal end **94**. The struts **88** may be made from metal or plastic material including but not limited to one or more elements of high strength material such as stainless steel or MP35N, or may preferably be made from shape memory or pseudoelastic alloys such as NiTi, or any of a variety of known structure biodegradable materials (e.g. polyglycolic acid, polylactic acid, poly-L-lactic acid and derivatives or copolymers such as PLGA).

[0090] Preferably, the struts **88** are self-expanding between a collapsed configuration and an open or expanded configuration, although they may also be

mechanically deployed. In the expanded configuration, the struts **88** expand radially outward to define a generally spherical or funnel-shaped volume. The struts **88** may be integrally formed, or may be separately attached to a hub at proximal point **92**. The membrane **90** may be attached to the struts **88** by a suitable method such as gluing, welding, sewing or other suitable method, and may expand to an open configuration to define an interior volume through movement of the struts. The membrane **90** may be elastic or inelastic, and may comprise a single membrane attached to one side of the struts or a laminate structure applied to both sides of the struts. For example, the membrane **90** may be made of any material that is suitable for expansion with the struts, including, but not limited to, fabric, plastic material, latex, or rubber.

[0091] The struts **88** open radially outward to expand the membrane **90**. The expandable structure as shown has a proximal **92** and a distal **94** end. At the distal end **94**, an opening **96** is provided which is sized and configured to fit over an organ such as an ovary. As illustrated, the opening **96** can be circular, polygonal or may have any other shape as desired that is adapted to enclose an organ such as an ovarian pedicle.

[0092] In one embodiment, a drawstring **98** is provided near the edge of the opening **96** and is adapted to be pulled taut over a tissue pedicle to seal and lock the bag. The drawstring **98** may be made out of any stretchable, rubberband-like material or a non-stretchable material including but not limited to an elastic band, rubber band, suture material, etc., or any other desired material.

[0093] As illustrated in Figure 10, the drawstring **98** is closed using a trumpet valve **100**. It will be appreciated that other means may be used to close the expandable structure **110** as discussed above.

[0094] As illustrated in Figure 10, the expandable structure may also have additional openings or ports **112, 113** and **114** to allow for insertion of surgical instruments as described above. These ports **112, 113** and **114** may be placed at desired locations on the outside of the expandable structure **110** to allow for the insertion of appropriate surgical instruments at desired locations. More particularly, these ports may be provided on the membrane **90** in a similar manner to that of the inflatable bag as described above.

[0095] The expandable structure **110** may be converted from the expanded configuration to the collapsed configuration and withdrawn from the body cavity via the loop **116** at the proximal end **92** of the expandable structure. This loop may be separately attached to the struts, or may be integrally formed with the struts. The loop may be used to attach the expandable structure to a laporoscopic device (shown in Figure 13), used to deliver and retrieve the expandable structure from the body.

[0096] The expanded configuration is shown in Figure 10 illustrates an insertion housing **118** used in one embodiment to insert the expandable structure **110** into a patient. As illustrated in more detail in Figure 11, the insertion housing is similar to the insertion housing described above and includes a tubular body **120** having a proximal end **122** corresponding to the proximal end **92** of the expandable structure **110** and a distal end **124** corresponding to the distal end **94** of the expandable structure. The insertion housing may be made of any relatively hard, biologically non-reactive material as discussed above, including but not limited to plastic materials.

[0097] In a collapsed configuration, the expandable structure **110** is adapted to fit inside an insertion housing **118**. Figure 11 illustrates the expandable structure **110** inside the insertion housing **118** before insertion into the body in the collapsed configuration. In one embodiment the struts **88** are squeezed together like a spring. While this embodiment is self-expanding, non-self-expanding expandable structures are also within the scope of the invention. Similar to the inflatable bag embodiment described above, the expandable structure **110** can be removed from the housing by using laporoscopic instruments to pull the expandable structure **110** out of the housing. Upon removal from the housing, the expandable structure **110** in the embodiment illustrated self-expands to its open configuration.

[0098] Figure 12 illustrates the expandable structure **110** placed around an ovary **72** having a cyst **74** with the drawstring **98** tightened around the ovarian pedicle **82**. Positioning of the bag is facilitated by the laparoscope **68** and the laporoscopic instruments **76** and **78** that can be inserted into the abdomen. In one embodiment, the ports **112**, **113**, and **114** on the membrane **90** attached to the struts **88** of the expandable structure **110** are generally lined up with the trocar sleeves **66**, **64**, and **60** (not shown in Figure 12) discussed

above. As discussed with respect to other embodiments above, one or more external markings help in alignment of the ports with the trocar sleeves. Further details regarding procedures and techniques that can be used are described with respect to the inflatable bag embodiment above.

[0099] Figure 13 illustrates the expandable structure **110** after the cyst **74** is removed and all of the fluid has been suctioned out, as described in the embodiment illustrated above. The ovary has been removed from the expandable structure **110** and the drawstring **98** tightened to close the opening **96** at the distal end **94** of the expandable structure **110**. The expandable structure **110** is then pulled out of a body cavity through a trocar sleeve **126**, using a laporoscopic grasper **76** engaging the loop **116**. In one embodiment, as the expandable structure is pulled out of the body cavity into the trocar sleeve, the struts **88** pull together and collapse within the trocar sleeve to the collapsed configuration. Figure 14 illustrates as the expandable structure **110** enclosing the cyst **74** is pulled into the trocar sleeve **126**, the struts **88** are squeezed together to allow the expandable structure **110** to be brought to the outside of the body cavity through the trocar sleeve **126**.

[0100] In some instances, it may not be possible to align the expandable structure **110** such that the ovary **72** or other intact organ are enclosed. An alternate form of the invention is shown in Figure 15 in which the struts **88** expand radially outward to form a bowl-like or cup-like surface **128**. The struts **88** can be straight or curved or hinged when expanded. The angle between the outer ends of the strut **88** and the central axis of the expandable structure **110** may approach about 90°. Preferably, the angle between the outer ends of the strut **88** and the central axis of the expandable structure **110** is between about 45° and about 80°. The depth of the bowl **128** defines an interior volume sufficient to capture any fluid or particles that may be formed during the surgery.

[0101] As shown in Figure 16, in this configuration the expandable structure **110** provides a bowl-like or cup-like surface **128** positioned under the ovary **72** having a cyst **74**. Similar delivery methods as described above may be used. In a preferred embodiment, the expandable structure **110** is introduced via an insertion housing **118** (not shown in Figure 16). The cyst **74** is removed from the ovary **72** assisted by the laparoscope **68** and laparoscopic instruments **76**. In this embodiment, the expandable structure **110** is used as a container to

collect leakage from the surgical procedure and may partially encapsulate the ovary **72** or the bowl **128** can simply be placed below the ovary **72** or other organ or location to be treated. The ovary **72** is positioned above the expandable structure **110**. The leakage from the surgical procedure is aspirated from the bowl **128** of the expandable structure. The bowl **128** is cleaned and then the expandable structure **110** is capsized and removed. The cyst tissue may be removed through the trocar sleeve (not shown). Alternatively, the cyst may be held within the expandable structure **110** and withdrawn as the capsized expandable structure **110** is withdrawn.

[0102] Preferred embodiments of the present invention allow for excision of a mass such as a cyst after the organ containing the mass, such as an ovary, has been encapsulated in the bag or expandable structure or by placing the expandable structure under the mass to be excised to provide a partial encapsulation of the mass as described above. Of course, the expandable structures described herein may be any size or shape to accommodate the mass to be removed and as determined by the nature of the particular surgery. The expandable structure need not include struts and a membrane. Any suitable expandable structure may suffice. The disclosed bag or expandable structure will allow surgical operation on the ovary without spilling the contents of the cyst into the peritoneal cavity. Consequently, there is a greatly reduced risk of peritonitis from spillage of a dermoid or mucinous cyst and also a greatly reduced risk of contamination of the peritoneal cavity with cancer cells if the cyst turns out to be malignant. Thus, a laparoscopic cystectomy can be performed regardless of the nature and the size of the cyst which is a big advantage for the patient in terms of shorter recovery time, fewer complications and fewer unnecessary oophorectomies and laparotomies. Of course, if the cyst turns out to be malignant, then additional surgery will be necessary. But if it isn't, then the patient would have benefited greatly from the laparoscopic approach. The bag or expandable structure also prevents inadvertent injury to the surrounding structures such as the bowels or the bladder and since the cyst is already deflated during the procedure, the transport of the cyst outside the abdominal cavity is also simplified for the physician.

[0103] It will be understood by those of skill in the art that numerous and various modifications can be made without departing from the spirit of the present invention.

Therefore, it should be clearly understood that the forms of the present invention are illustrative only and are not intended to limit the scope of the present invention.